DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 20, 2015

Sterilucent, Inc.
Peter Kalkbrenner
Director of Engineering
1400 Marshall Street NE
Minneapolis, MN 55413

Re: K142109
Trade/Device Name: Sterilucent Sterilization Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Container
Regulatory Class: II
Product Code: KCT
Dated: December 19, 2014
Received: December 22, 2014

Dear Mr. Kalkbrenner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142109

Device Name
Sterilucent Sterilization Container System

Indications for Use *(Describe)*
The Sterilucent Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. This container system is intended to be used in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen Cycles. The sterility maintenance period has been validated for a period of up to 180 days.

Reusable baskets and accessory items (clips, posts, pins, dividers, brackets, bars and mats) are intended to organize and secure enclosed medical devices during sterilization, transport, and storage of the container.

Consumable accessory items (filter media, data card and tamper evident arrows) provide a range of functions and are indicated as single-use devices. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Data cards are used to record information regarding a specific sterilization process load. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains an external process indicator that serves as a visual indication that the system has been exposed to the Sterilucent VHP sterilization process.

(Continued on separate page.)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Indications for Use Continuation page
(Form FDA 3881 (1/14)

Container and Accessory Device Challenges

Container Catalog #	Basket Catalog #	Contents/Configuration	Sterilization Cycle	
			Lumen Cycle	Non-Lumen Cycle
SL065 SL066 SL067 SL068 SL069 SL070 SL071 SL072 SL073 SL074 SL075 SL076 SL077 SL078 SL098	SL011 SL012 SL013 SL014 SL015 SL016 SL017 SL018 SL019 SL020 SL021 SL022 SL023 SL024 SL025 SL026 SL027 SL028 SL029 SL030 SL031 SL032 SL033 SL034 SL035 SL036 SL037 SL038 SL039 SL040 SL041 SL042 SL043 SL044 SL045 SL046 SL047 SL048 SL049 SL050	Baskets	YES	YES
		Stacking Baskets	YES	YES
		Lumen: 1mm (ID) or larger x 60mm (L) or shorter	YES Qty. 10	NO
		Lumen: 2mm (ID) or larger x 250mm (L) or shorter	YES Qty. 10	NO
		Lumen: 3mm (ID) or larger x 350mm (L) or shorter	YES Qty. 10	NO
		Occluded/Mated Challenge	YES	YES
		Silicone Support Bars	YES	YES
		Dividers	YES	YES
		Brackets	YES	YES
		Silicone Mat	YES	YES
		Filter	SL082 SL083 SL084	SL082 SL083 SL084
		Data Card	SL081	SL081
		Tamper-Evident Arrow	SL085	SL085
		Stack Height	NO STACKING	NO STACKING
		Max. Total Container System Weight	10 lbs (4.5 kg)	25 lbs (11.3 kg)

Maximum Container Loads

Catalog Code	Container Description	External Dimensions	Total Container Plus Load Weight	
			Lumen Cycle[1]	Non-Lumen[2]
SL065	Mini	10.2” x 7.2” x 3.2”	5 lbs (2.3 kg)	5 lbs (2.3 kg)
SL066	Quarter Length	9.5” x 12.4” x 3.8”	8 lbs (3.3 kg)	8 lbs (3.3 kg)
SL067	Half Length, 4" Deep	11.8” x 12.4” x 4.5”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL068	Half Length, 5" Deep	11.8” x 12.4” x 5.3”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL069	Half Length, 6" Deep	11.8” x 12.4” x 6.1”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL070	Mid Length, 4" Deep	19.2” x 12.4” x 4.5”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL071	Mid Length, 5" Deep	19.2” x 12.4” x 5.3”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL098	Mid Length, 6" Deep	19.2” x 12.4” x 6.1”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL072	Mid Length, 8" Deep	19.2” x 12.4” x 7.8”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL073	Full Length, 4" Deep	23.1” x 12.4” x 4.5”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL074	Full Length, 5" Deep	23.1” x 12.4” x 5.3”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL075	Full Length, 6" Deep	23.1” x 12.4” x 6.1”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL076	Full Length, 7" Deep	23.1” x 12.4” x 7.0”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL077	Small Narrow, 3" Deep	20.8” x 7.3” x 3.9”	10 lbs (4.5 kg)	10 lbs (4.5 kg)
SL078	Small Narrow, 5" Deep	20.8” x 7.3” x 5.2”	10 lbs (4.5 kg)	10 lbs (4.5 kg)

[1] The Lumen Cycle validation testing was conducted using a maximum of ten (10) lumens per load. The validation studies were performed using the following device models and weights:

Model	SL065	SL066	SL069	SL072	SL076	SL078
Validation Load Weight (lbs.)	5.1	8.0	10.3	14.0	17.1	10.1

[2] The Non-Lumen Cycle validation studies were performed using the following device models and weights:

Model	SL065	SL066	SL069	SL072	SL076	SL078
Validation Load Weight (lbs.)	5.0	8.0	12.1	20.1	25.1	10.1

[3] Two (2) containers, each containing 12 lbs. (5.4 kg), for a total chamber load weight of 24 lbs. (10.8 kg), has also been validated for use in the PSD-85 Non-Lumen Cycle.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
for the
Sterilucent Sterilization Container System
K142109

Owner:	Sterilucent, Inc.
Address:	1400 Marshall Street NE Minneapolis, MN 55413
Telephone:	612-767-3260
Fax:	612-767-3261

Contact:	Peter R. Kalkbrenner Director of Engineering
Telephone:	612-767-3253
Fax:	612-767-3261

Summary Date: 16 January 2015

1. Device Name and Classification

Trade Name:	Sterilucent Sterilization Container System
Common/Usual Name:	Sterilization Container
Classification Name:	Sterilization Wrap, Containers, Trays, Cassettes & Other Accessories
Product Code:	KCT (21 CFR 880.6850)
Class:	II

2. Predicate Device

Genesis™ Reusable Rigid Container System (K112535)

3. Device Description

The Sterilucent Sterilization Container System is an assortment of rigid, reusable, stackable containers that are used to sterilize other medical devices and maintain sterility of those devices until used. The container system is comprised of a lid, bottom, filter, tamper evident arrows, and data cards.

The container system houses reusable baskets of varying depths and organizing accessory items that are used to organize and secure surgical instrumentation and/or other medical devices.

4. Statement of Intended Use:

The Sterilucent Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The container system is intended to be used in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen Cycles. The sterility maintenance period has been validated for a period of up to 180 days.

Reusable baskets and accessory items (clips, posts, pins, dividers, brackets, bars and mats) are intended to organize and secure enclosed medical devices during sterilization, transport, and storage of the container.

Consumable accessory items (filter media, data card and tamper evident arrows) provide a range of functions and are indicated as single-use devices. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Data cards are used to record information regarding a specific sterilization process load. Tamper evident arrows provide a

visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains an external process indicator that serves as a visual indication that the system has been exposed to the Sterilucent VHP sterilization process.

Container and Accessory Device Challenges

Container Catalog #	**Basket Catalog #**	**Contents/Configuration**	**Sterilization Cycle**	
			Lumen Cycle	Non-Lumen Cycle
SL065 SL066 SL067 SL068 SL069 SL070 SL071 SL072 SL073 SL074 SL075 SL076 SL077 SL078 SL098	SL011 SL012 SL013 SL014 SL015 SL016 SL017 SL018 SL019 SL020 SL021 SL022 SL023 SL024 SL025 SL026 SL027 SL028 SL029 SL030 SL031 SL032 SL033 SL034 SL035 SL036 SL037 SL038 SL039 SL040 SL041 SL042 SL043 SL044 SL045 SL046 SL047 SL048 SL049 SL050	Baskets	YES	YES
		Stacking Baskets	YES	YES
		Lumen: 1mm (ID) or larger x 60mm (L) or shorter	YES Qty. 10	NO
		Lumen: 2mm (ID) or larger x 250mm (L) or shorter	YES Qty. 10	NO
		Lumen: 3mm (ID) or larger x 350mm (L) or shorter	YES Qty. 10	NO
		Occluded/Mated Challenge	YES	YES
		Silicone Support Bars	YES	YES
		Dividers	YES	YES
		Brackets	YES	YES
		Silicone Mat	YES	YES
		Filter	SL082 SL083 SL084	SL082 SL083 SL084
		Data Card	SL081	SL081
		Tamper-Evident Arrow	SL085	SL085
		Stack Height	NO STACKING	NO STACKING
		Max. Total Container System Weight	10 lbs (4.5 kg)	25 lbs (11.3 kg)

Maximum Container Loads

Catalog Code	Container Description	External Dimensions	Total Container Plus Load Weight	
			Lumen Cycle[1]	Non-Lumen[2]
SL065	Mini	10.2” x 7.2” x 3.2”	5 lbs (2.3 kg)	5 lbs (2.3 kg)
SL066	Quarter Length	9.5” x 12.4” x 3.8”	8 lbs (3.3 kg)	8 lbs (3.3 kg)
SL067	Half Length, 4" Deep	11.8” x 12.4” x 4.5”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL068	Half Length, 5" Deep	11.8” x 12.4” x 5.3”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL069	Half Length, 6" Deep	11.8” x 12.4” x 6.1”	10 lbs (4.5 kg)	12 lbs[3] (5.4 kg)
SL070	Mid Length, 4" Deep	19.2” x 12.4” x 4.5”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL071	Mid Length, 5" Deep	19.2” x 12.4” x 5.3”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL098	Mid Length, 6" Deep	19.2” x 12.4” x 6.1”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL072	Mid Length, 8" Deep	19.2” x 12.4” x 7.8”	10 lbs (4.5 kg)	20 lbs (9.1 kg)
SL073	Full Length, 4" Deep	23.1” x 12.4” x 4.5”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL074	Full Length, 5" Deep	23.1” x 12.4” x 5.3”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL075	Full Length, 6" Deep	23.1” x 12.4” x 6.1”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL076	Full Length, 7" Deep	23.1” x 12.4” x 7.0”	10 lbs (4.5 kg)	25 lbs (11.3 kg)
SL077	Small Narrow, 3" Deep	20.8” x 7.3” x 3.9”	10 lbs (4.5 kg)	10 lbs (4.5 kg)
SL078	Small Narrow, 5" Deep	20.8” x 7.3” x 5.2”	10 lbs (4.5 kg)	10 lbs (4.5 kg)

[1] The Lumen Cycle validation testing was conducted using a maximum of ten (10) lumens per load. The validation studies were performed using the following device models and weights:

Model	SL065	SL066	SL069	SL072	SL076	SL078
Validation Load Weight (lbs.)	5.1	8.0	10.3	14.0	17.1	10.1

[2] The Non-Lumen Cycle validation studies were performed using the following device models and weights:

Model	SL065	SL066	SL069	SL072	SL076	SL078
Validation Load Weight (lbs.)	5.0	8.0	12.1	20.1	25.1	10.1

[3] Two (2) containers, each containing 12 lbs. (5.4 kg), for a total chamber load weight of 24 lbs. (10.8 kg), has also been validated for use in the PSD-85 Non-Lumen Cycle.

5. Technological Characteristics Summary Comparison

The Sterilucent Sterilization Container System has similar technological characteristics as the predicate device:

Summary of Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	**New Device** ***Sterilucent Sterilization Container System*** ***K142109***	**Predicate Device** ***Genesis™ Reusable Rigid Container System*** ***K112535***
Container	5000 and 1100 Series Anodized Aluminum; 300 Series Stainless Steel	Same
Container Gasket	Closed Cell Silicone Foam	Same
Reusable Baskets	304 Electropolished Stainless Steel	Same
Clips, Posts, Pins	300 and 400 Series Stainless Steel	Same
Dividers, Brackets	5000 Series Aluminum	Same
Bars, Mats	Silicone Elastomer	Same
Filter Material	SMS Polypropylene	Same
Data Card	High-Density Polyethylene (Tyvek®)	Same
Tamper Evident Arrow	Polypropylene	Same
Arrow Process Indicator	Synthetic Substrate printed with Reactive Ink	Same
Sterilization Modality	Vaporized Hydrogen Peroxide (VHP)	Same (some models also approved for steam and ETO)
Indications for Use	The Sterilucent Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The container system is intended to be used in the Sterilucent PSD-85 Hydrogen Peroxide Sterilizer Lumen and Non-Lumen Cycles. Reusable baskets and accessory items (clips, posts, pins, dividers, brackets, bars and mats) are intended to organize and secure enclosed medical devices during sterilization, transport, and storage of the container.	The Genesis Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used for a maximum of 180 days. Containers are suitable for dynamic air removal (pre-vacuum) steam sterilization, immediate

	Consumable accessory items (e.g. filter media, data card and tamper evident arrows) provide a range of functions and are indicated as single-use devices. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Data cards are used to record information regarding a specific sterilization process load. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains an external process indicator that serves as a visual indication that the system has been exposed to the Sterilucent VHP sterilization process.	use pre-vacuum steam sterilization and 100% ethylene oxide sterilization when used as described in the instructions for use. Reusable baskets and accessory items (pins, dividers, mats, etc) are intended to organize and secure enclosed medical devices during sterilization, transport, and storage of the container. Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization parameter. Data cards, filters and tamper evident arrows are single use only.

6. Summary of Non-Clinical Performance Data

Sterilization performance studies were conducted for the Sterilucent Sterilization Container System and all acceptance criteria were met. Sterilization efficacy testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method and half-cycle validation under worst case conditions. Real time event related shelf life studies demonstrated sterility maintenance for a 180 day time period. Whole

package microbial challenge testing, exposing a container to a minimum of 1 x 10^6 *Bacillus atrophaeus* colony forming units (CFU) via an aerosol challenge, demonstrated appropriate microbial barrier properties following exposure to the Sterilucent hydrogen peroxide sterilization processes under worst case conditions.

7. Summary of Clinical Performance Data

N/A – No clinical tests were conducted for this submission.

8. Overall Performance Conclusion Statement

The non-clinical studies demonstrated that the Sterilucent Sterilization Container System is as safe, as effective, and performs as well as the predicate device for the sterilization of the enclosed medical devices and maintains sterility of those devices for a period of up to 180 days. The proposed device and the predicate device are composed of the same designs, materials, and manufacturing characteristics. The proposed device is substantially equivalent to the predicate device.